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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/051,685 | 04/17/1998 | SAM D. SANDERSON | UNMC63102 | 8287 |

7590 03/07/2002

Christopher M. Goff
Senniger, Powers, Leavitt & Roedel
One Metropolitan Square, 16th Floor
St Louis, MO 63102

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| EXAMINER |
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SAUNDERS, DAVID A

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| ART UNIT | PAPER NUMBER |
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1644
DATE MAILED: 03/07/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | | |
|-----------------|----------|----------------|-----------------|
| Application No. | 051,685 | Applicant(s) | SANDERSON et al |
| Examiner | SAUNDERS | Group Art Unit | 1644 |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

Responsive to communication(s) filed on 10/10/01

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

Claim(s) 1, 3-17, 25 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) 1, 3-17, 25 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892 Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948 Other _____

Office Action Summary

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1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 3-17, drawn to molecular adjuvant constructs.

Group II, claim(s) 25, drawn to antibodies obtained by immunizing with molecular adjuvant constructs.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group II encompasses any antibody preparation (polyclonal or monoclonal) of the prior art. Nothing in applicant's disclosure shows that the antibodies, produced as a product by process, would be any different from antibodies produced by other processes in terms of their binding specificities and/or effector functions. Therefore applicant has not made a contribution over the prior art which provides for unity of invention.

Further, neither claim 25 nor any claim to an antibody was examined by the IPEA. Therefore, claim 25 cannot be considered to enjoy any status of falling within the unity of invention encompassed by the application, as filed at the International Stage.

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Further, the fact that the record shows claim 25 as separately rejected over prior art from claims 1 and 3-17 points to their separated patentability.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

applicant must elect a species of antibody obtained by immunizing with a construct containing particularly disclosed targeting ligand (e.g. to C5a receptor, to C3d receptor, etc.), since such targeting may determine the isotype of antibody which may result from the immunization. Also applicant must elect, in combination therewith, an antibody against a particular subgenus of antigens/immunogens (e.g. glycoproteins, phosphoproteins, lipoproteins , carbohydrates, etc.) as disclosed at page 9.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:
none

The following claim(s) are generic: 25

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the antibodies are known in the prior art. If applicant contemplates that he has produced an antibody that is any different from that obtained against the same antigen by another method, he must make an election in terms of the targeting ligand used and in terms of the antigen subgenus or antigen species to which the antibody binds.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Saunders whose telephone number is (703) 308-3976.

DAS

January 21, 2002

David E. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182 1644